Remarks

Claims 1-2 and 11-15 stand rejected as obvious over US Patent Nos. 5,723,228 or 4,357,272 in view of US Patent No. 5,688,682 and Beasley. Claim 5 stands rejected as obvious over US Patent Nos. 5,723,228 or 4,357,272 in view of US Patent No. 5,688,682 and Beasley in further view of McAdam. Claims 6 and 8-9 stand rejected as obvious over US Patent Nos. 5,723,228 or 4,357,272 in view of US Patent No. 5,688,682 and Beasley in further view of Deignan and Akita. Claims 7 and 10 stand rejected as obvious over US Patent Nos. 5,723,228 or 4,357,272 in view of US Patent No. 5,688,682 and Beasley and in further view of Akita or Hatta.

Applicants again traverse the rejections of the present claims for obviousness and contend that the Examiner has engaged in an impressible hindsight reconstruction of the prior art. Moreover, the Examiner has not demonstrated the requisite motivation or reasonable expectation of success for the present invention.

US Patent Nos. 5,723,228 ('the '228 patent') and 4,357,272 ('the '272 patent') and presents antibodies raised from hens through egg yolk. The '272 patent, in column 1, lines 19-22, column 5, lines 39-48, states that it relates to the use of antibodies in diagnostics, antibodies against pathogens, and against venine poision and the '228 patent is related to tuberculosis. Therefore, these references suggests the following.

(1) The egg yolk antibodies developed are very specific and defined in their functions. In other words these antibodies are useful for under only pathological conditions. This means such antibodies are useful against pathogens only. In other words the developed antibodies can only function under pathological conditions.

(2)The focus of these reference is very specific and narrow, confining itself to only antibodies raised against pathogens. In other words these references are aimed at developing antibodies against pathogens using the hen as a system.

Both of these references provide the same method of preparing antibodies i.e. by means of egg yolk antibodies, but the basic object of both references is different than that of the there present invention and therefore these references do not provide proper motivation.. The '272 patent identifies the application of the antibodies prepared by egg yolk as diagnostic agent, treatment of pathological conditions, and anti-venom. The '228 patent on the other hand identifies the application of the antibodies against intestinal parasitosis. Since intestinal

parasitosis is a pathological condition and that the '228 patent acknowledges on column 1, lines 55-70, and beginning of column 2 that egg yolk antibodies can be raised/developed against this pathogen. Therefore, none of references provide motivation for combination with Beasley.

Claim 5 stands rejected as obvious over US Patent Nos. 5,723,228 or 4,357,272 in view of US Patent No. 5,688,682 and Beasley in further view of McAdam. To this applicants submit that the antibodies raised in these references are from a mammal (i.e. a rabbit) which cannot be similar to antibodies raised from a egg laying bird like the hen. It is impossible to derive any motivation from these references where the organisms for developing are phylogenetically dissimilar. It is further submitted that the field of immunology is too unpredictable for a person skilled in art to arrive at the conclusion that antibodies raised from a mammal like rabbit can also be raised from a non-mammal egg laying animal like hens.

Likewise the '272 and '228 patents cannot be combined with Beasely *et at*, to arrive at the present invention. The claim by the examiner that antibodies generated in rabbits (Ig G) are similar to poultry antibodies (IgY) is incorrect. The rabbit antibodies have a molecular weight of 10,000 daltons while that of poultry have a molecular weight of 19,000 daltons. The structure of the two antibodies is also different. The egg yolk antibodies have three carbohydrate moieties while the rabbit antibody has only two carbohydrate moieties (Fig.1). The rabbit antibody has a hinge region, while the egg yolk antibodies lack it. In addition there is no disclosure in the any of the cited references that yolk antibodies can be raised against small molecules. There are no results and findings in any of the references that establish the fact of egg yolk antibodies can be raised against small molecule pesticides. Even hypothetically if the references are combined the egg yolk antibodies against small molecules would not be reasonably expected.

Immunogenecity is not an intrinsic property of an antigen, but rather depends on a number of properties of the particular biological system that the antigen encounters. It is dependent on its foreignness, molecular size, chemical composition and complexity and ability to be processed and presented with an MHC molecule on the surface of an antigen presenting cell or altered self cell. The immune response in the rabbits and poultry is different in that the rabbit has 5 classes of immunoglobulins while in the poultry there are only 3 types of immunoglobulins.

Therefore the mechanism by which the immune response of the rabbit responds to the same antigen (i.e. small pesticide molecules as of the present invention) is different when compared to its response in poultry. This is the reason, where in the poultry antibodies can be raised against small molecules, such as haptens without conjugating to a protein, while in the rabbit it is impossible to do so. The poultry eggs have ovalbumin and the hen would have self antibodies against ovalbumin. Thus, the BSA system is best when compared to OVA. BSA conjugate does not matter in chicken is incorrect. This because the ovalbumin in chicken will not elicit an immune response.

On Page 7, lines 15-18 the Examiner states "given the steps of making the antigen and the antigens are the same as that if the reference teachings....." In response, applicants submit that it is necessary to understand in the cited references and in the present invention the animals used are phylogenetically dissimilar and therefore the antigen–conjugate would not necessarily bind to the same organochlorine pesticide or its analog because the epitopes or functional groups it recognizes between two rabbits itself would be different i.e. rabbits and poultry are phylogentically different animals and because of this the egg yolk antibodies yield an unexpectedly a large amount of antibody thereby helping in obtaining better reproducible results and assay systems, in contrast to rabbit antibodies.

An immune response (defense mechanism) is trigerred only if the injected antigen (immunogen) is foreign/ toxic to the animal and reaction to this is production of antibody. The dose should be such that it triggers enough antibody production but is not lethal to the animal. Thus the examiner's argument that the antigen–conjugate is non-toxic to the rabbit (Beasley) and thus produced good antibody response has no reasonable scientific basis..

Further, specific site conjugation or binding specificity cannot be arrived from the Beasely reference because the nature of antibodies in the present invention and the cited references are different i.e. the specific site of conjugation or binding specificity cannot be recited as the antibodies are polyclonal in nature. None of the other cited references (Deignon, Akita or Hatta) remedy the deficiencies of the examiner's arguments.

The way the antibodies will react and raised in the cited references will not be same as in the present invention because:

(a) The antigens used are structurally and functionally different;

(b) The antibodies raised and developed are differently;

(c) What works in rabbits cannot be predicted with reasonable certainty to work in hens since they are different phylogenetically; and

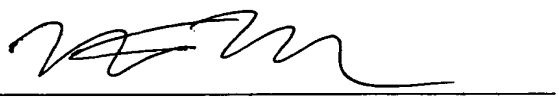
(d) The chemical pesticides of the cited references are different than that of the present invention and it cannot be arrived at mere reading. One needs to conduct thorough experiments to establish such suggestions. Chemical pesticides being antigens elicit antibody production.

Conclusion

In light of these remarks and the evidence of the 132 Declaration and the arguments previously submitted, applicants urge that one of skill in the art would not have been motivated to combine the references cited by the Examiner. Nor would the skilled artisan have a reasonable expectation of success of the present invention. Finally, the interest in the commercialization of the present invention is evidence of non-obviousness. Therefore, applicants submit the obviousness rejections of record are improper and respectfully request withdrawal of these rejections.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,



Date June 13, 2005

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